Wessex Academic Health Science Network

Mid Hampshire Healthcare Cardiovascular Risk Review Pathway

Implementation Report

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Part of The AHSN Network

Contents

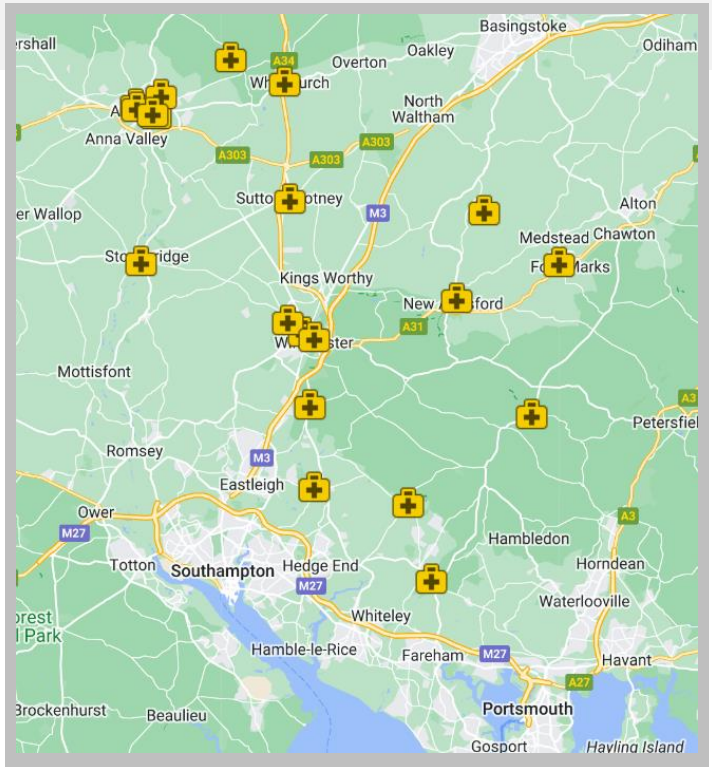
Introduction and purpose of the report

Mid Hampshire Healthcare (MHH) is a GP Federation created in 2014, covering the Winchester and Andover regions of Hampshire (4PCNs/18 practices*). In the first quarter of 22/23 MHH entered into a collaborative working partnership with Novartis** enabling the setup and launch of a lipid management clinic across the GP Federation practices, taking into consideration the new/updated lipid management pathway (https://www.england.nhs.uk/aac/wp-content/uploads/sites/50/2020/04/National-Guidance-for-Lipid-Management-Prevention-Dec-2022.pdf) and addressing the future of lipid management within Primary Care. The service is for secondary prevention and includes - where appropriate - the new injectable therapy inclisiran. Wessex Academic Health Science Network (AHSN) has provided project management resource and chairs the regular working group meetings. This report details the implementation journey to date and has been written by the AHSN team with input from the project working group. The purpose is to provide some initial insight into the implementation which may help MHH with future plans. It is not an evaluation of the effectiveness of the service as the available data is not sufficient to conduct a robust evaluation at this stage.

* Mid Hampshire Healthcare PCNs/Practices

PCN	Surgery
Winchester City	Friarsgate Practice
Winchester City	St Clements Surgery
Winchester City	St Paul's Surgery
Winch Rural North/East	Alresford Surgery
Winch Rural North/East	Gratton Surgery
Winch Rural North/East	Stockbridge Surgery
Winch Rural North/East	Watercress Medical/Mansfield Park Surgery
Winch Rural North/East	West Meon Surgery
Winch Rural North/East	Two Rivers/Whitchurch

PCN	Surgery
Winch Rural South	Bishops Waltham Surgery
Winch Rural South	Stokewood Surgery
Winch Rural South	Twyford Surgery
Winch Rural South	Wickham Surgery
Andover	Adelaide Medical Centre
Andover	Andover Health Centre
Andover	Charlton Hill Surgery
Andover	Shepherds Spring Medical Centre
Andover	St Mary's Surgery



Mid Hampshire Healthcare Practice locations

** https://www.novartis.com/uk-en/about/partnerships/collaborative-working

Mid Hampshire Healthcare Cardiovascular Risk Review Pathway

The latest version of the service pathway is opposite (figure 1). Patients are identified via an initial search run in the practice's clinical system either by the practice team or remotely via Mid Hampshire Healthcare (MHH) or the Hampshire and Isle of Wight central pharmacists' team. MHH review the results and manually identify patients who meet the criteria (age/lipid profile/correctly coded). A list of those identified by the initial search but not meeting the criteria is returned to the practice for review and potential optimisation of existing therapies (if required). Patients identified as being suitable follow the pathway (figure 1) involving an initial telephone call, cardiovascular risk review and blood test and follow up call with a GP/prescribing pharmacist who recommends treatment based on the results of the blood test and review. If the recommendation is to titrate existing medication or try alternative treatments, the patient is referred back to their practice. If inclisiran is suitable they are booked in for their initial loading dose and subsequent injections at an initial 3- and then 6-monthly intervals. If specialist guidance is required, MHH refer back to the patient's practice and/or consult with a consultant chemical pathologist.

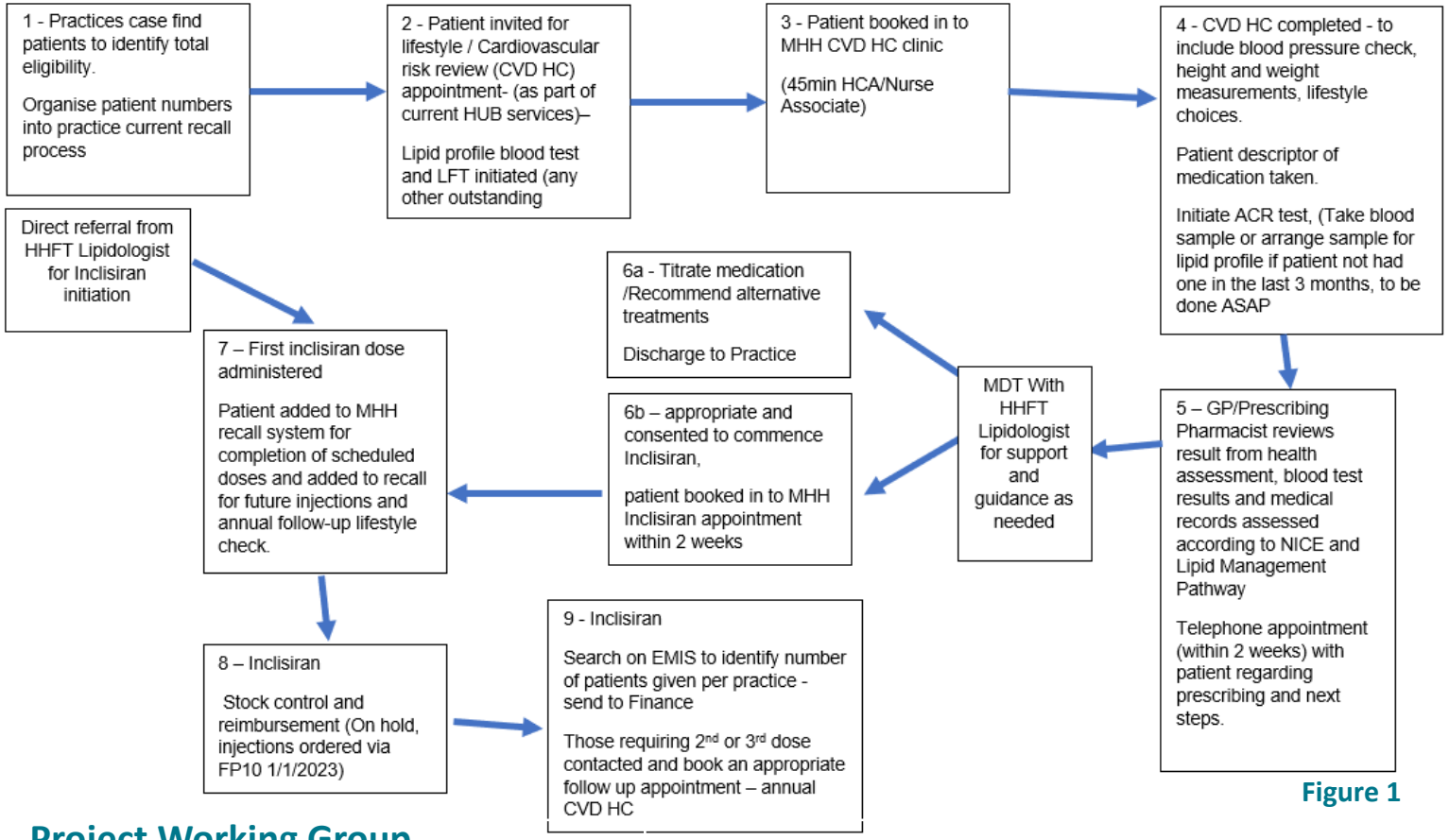


Figure 1

Project Working Group

Primary Care Nurse Consultant - MHH	Clinical Pharmacist - MHH
Clinical Lead/Nurse Manager – MHH	Clinical Director - MHH
Project Manager, Cardiac Risk Pathway - MHH	Programme Manager – Wessex AHSN
Business Operations Manager - MHH	Joint Head of Medicines Optimisation, North and Mid Hants – HIOW ICB
Non-Executive Director - MHH	South West System Lead Pharmacist – HIOW ICB

To what extent has the pathway been adopted by the practices?

To date (end of February 2023) 9 of the 18 practices (Figure 1) that make up the federation have agreed to take part in the project, have had patients identified via the system search/manual prioritisation process and that have either attended a clinic or are waiting to do so. There has been a total of 14 clinics since 03 January (see Figure 2) with more booked in for March and beyond.

Practice	Identified by initial search	Suitable for next phase - Initial telephone consultation	Attended a clinic	Follow up phone call	Outcome -Inclisiran prescribed
Gratton	38	12	10	7	3
Wickham	125	17	14	9	4
St Clements	80	13	Clinic 28th Feb		
Shepherds Spring	43	11	7	4	3
Stockbridge	66	10	5	4	4
Charlton Hill	67	14	11	6	?
Bishops Waltham	116	24	Clinics in March		
Two Rivers	80	12	5	5	1
Twyford	76	20	5	3	1

Figure 1

Clinic location	Date	Time	Number attended / max capacity	No shows	Outcome - inclisiran prescribed
Andover	03.01.23	17.00 - 19.00	3	0	2
Andover	04.01.23	18.00	1	0	1
Andover	14.01.23	09.00-12.45	4	1	3
South Wonston	19.01.23	10.00 -11.30	2	0	?
Andover	21.01.23	09.00-13.00	5	1	?
Wickham	21.01.23	09.00 -13.00	5	1	2/?
Andover	04.02.23	09.00-13.00	5	1	3/?
Wickham	04.02.23	09.00-13.00	5	1	?
Stokewood	04.02.23	09.00-12.00	4	0	1
Andover	11.02.23	09.00-12.00	5	1	?
Stokewood	17.02.23	N/A	1		?
Andover	18.02.23	09.00 - 13.00	5	0	?
Andover	24.02.23	N/A	1		?
St Clements Surgery	28.02.23	09.30 - 15.00	?	?	?

Figure 2

In the tables shown, not every patient that attends a clinic receives a follow up phone call/review i.e. if their LDL cholesterol is less than 2.6. All fields marked with a question mark are as a result of the data not being available at the end of February. We are still at a relatively early stage of the adoption process and it is anticipated that more practices will come onboard in due course.

What were the challenges and how were they overcome?

Challenges	Actions taken in response to each challenge
1. Identifying the patient cohort: the service is for secondary prevention and patients need to meet specific criteria to qualify	The search process has undergone a continuous cycle of improvement as the project has progressed and continues to do so. Both Ardens* and the UCLP Framework** have been utilised and the central ICB pharmacists' team have supported MHH by running searches for the practices. At this stage a manual process is required to filter the results and identify patients to call in to clinic e.g. at Shepherds Spring, 43 patients were initially identified with 11 suitable to attend a clinic. This is an essential but time consuming process that will hopefully be improved in the future. Once the initial cohort has been identified the search is then re-run three months later to identify any new patients.
2. Member practice engagement	Nine of the 18 practices have currently signed up to the project and have had patients identified via the search process. MHH appointed a project manager (cardiac risk pathway) in October 2022 which has helped significantly with practice engagement. There have also been two educational events aimed at raising practice awareness. Data sharing agreements are in place with all of the participating practices in support of robust information governance processes.
3. Reluctance to attend evening clinics	Early feedback from patients reflected a reluctance to attend clinics in the evening. This was in part attributed to the time of year (winter), being dark and with potentially difficult driving conditions. MHH responded to the needs of their patients and now schedule almost all of their clinics during the day (mainly Saturday) and have a much better uptake (see Figure 2 on page 5).

* https://www.ardens.org.uk/

** Search and risk stratification tools - UCLPartners

What were the challenges and how were they overcome?

Challenges	Actions taken in response to each challenge
4. Addressing the needs of patients identified by the initial search but not meeting the criteria to be booked into a clinic	An ongoing discussion point at the working group meetings has been the need for the service to be a part of the wider CVD pathway. On this basis, patients identified by the initial search (691 across the 9 practices) but not meeting the criteria to be invited to a clinic (558 which equates to 81%) are referred back to the prescribing lead at the practice or the PCN pharmacy team. This ensures the opportunity is not missed to review and amend their existing medication/treatment.
5. Prescribing restrictions for a federation	As a federation MHH don't have a General Medical Services (GMS) or Personal Medical Services (PMS) contract, so are unable to order medication and claim back via FP34 forms. This means they cannot order inclisiran and claim the £10 administration fee. A number of workarounds have been trialled and patients are currently required to collect the medication from their local pharmacy and bring it with them to their appointment, so that the injection can be administered. Although a functional temporary solution this is not ideal and it is hoped that legislation will be changed in the future so that federations and similar organisations are able to hold a GMS contract. The working group continues to explore alternative solutions with the support of the AHSN national inclisiran team and with the ambition to establish (with NHS England) a mechanism for at-scale delivery of lipid management.

Patient feedback/case studies

At the time of publication, two patients have followed the new pathway through from start to finish and have received both of their initial doses of Inclisiran, with a three month interval. Future injections (maintenance) will now be at 6-monthly intervals.

The case studies (shown on the right) map their journey through the new service and how the treatment to date has affected their cholesterol levels. Data has been obtained via a patient satisfaction survey, the service provider and a follow up interview where possible. Feedback from the patients has been overwhelmingly positive and their cholesterol levels have improved from the initial baseline blood test to the second test performed 8 weeks after the initial injection.

Both of these examples involve inclisiran but it is important to note that it is not the only outcome from the service. Patients suitable for titration of their existing medication are referred back to their practice to action the recommendation. Patients identified with other conditions such as high blood pressure are encouraged to visit their GP to discuss treatment options. The face-to-face appointment also reviews and offers lifestyle advice.

Case Study 1 ●

65yr old male with a family history of high cholesterol

Coronary angioplasty and stent insertion to relieve a blocked artery	2014
• Existing medication: - Amlodipine 5mg - Rampiril 10mg - Aspirin 75mg - Rosuvastatin 40mg	
• Initial phone call with nurse and invitation to a lifestyle/cardiovascular risk review	1/9/22
• Face to face lifestyle/cardiovascular risk review with nurse	8/9/22
• Initial blood test results - Cholesterol 4.6 - Triglyceride 2.36 - HDL 0.97- LDL 2.6 - Cholesterol HDL Ratio 4.7	Sept 22
• Clinical review via phone with GP with recommendation to commence treatment – inclisiran (case also discussed with a consultant chemical pathologist)	21/9/22
• Inclisiran first dose	24/11/22
• 2nd blood test results - Cholesterol 3.4 - Triglyceride 1.78 - HDL 1.19 - LDL 1.4 - Cholesterol HDL Ratio 2.9	Feb 23
• Inclisiran second dose	24/2/23

Case Study 2 ●

79yr old male

Stent insertion in the left anterior descending artery (LAD)	2011
• Existing medication: - Atenolol 50mg - Aspirin 75mg - Omeprazole 40mg - Atorvastatin 80mg -Tamsulosin 400microgram	
• Initial phone call with nurse and invitation to a lifestyle/cardiovascular risk review	1/9/22
• Face to face lifestyle/cardiovascular risk review with nurse	8/9/22
• Initial blood test results - Cholesterol 7.0 - Triglyceride 4.68 - HDL 1.07 - Cholesterol HDL Ratio 6.5 - LDL – Unable to calculate as riglyceride >4.5	Sept 22
Clinical review via phone with GP with recommendation to commence treatment – inclisiran	21/9/22
Inclisiran first dose	24/11/22
Second blood test results - Cholesterol 4.0 - Triglyceride 1.31 - HDL 1.27 - LDL 2.1 - Cholesterol HDL Ratio 3.1	Feb 23
Inclisiran second dose	24/2/23

Patient feedback/case studies

	Not relevant to this consultation	No, not at all	No, not really	Yes, but not fully	Yes	Yes, completely
The service has given me an increased knowledge and awareness relating to my cholesterol levels.						●●
At every stage of the process things were explained to me in a clear and concise manner.						●●
Were you involved as much as you wanted to be in decisions about your care and treatment?						●●
Do you have confidence in the decisions made about your cholesterol levels or treatment?						●●
At every stage of the process were you encouraged to ask questions?					●	●
Were all of your questions answered to a level you were satisfied with?						●●
Were you treated with respect and dignity at every stage of the process?						●●
Is your treatment so far achieving the desired results?						●●
Overall, have your experiences with Mid Hampshire Healthcare's new lipid management service been satisfactory?						●●

Staff feedback

Six members of staff involved with the delivery of the project completed the NoMad* (implementation measure based on Normalisation Process Theory) survey, designed specifically to understand how new technologies and complex interventions are applied and integrated in health care. Employment duration ranged from less than 1 year to 3-5 years and a range of roles are represented from those involved in the design/ongoing development of the service through to those delivering on the ground. Familiarity with the service varied which is to be expected, given that some members of staff were new to the organisation. They did however feel that the service would become a normal part of their work in the future. The general feeling was that there is a good understanding of the service (C - page 11) and it is adequately supported by management (4 of 6) and of value to patients (C3 - page 12). All surveyed are open to new ways of working and plan to continue supporting the service (C2 - page 11).

Individual responses are represented by the following coloured dots:

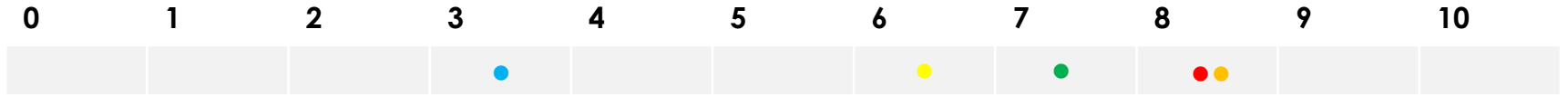
How many years have you worked for/with Mid Hampshire Healthcare?

How would you describe your professional job category?

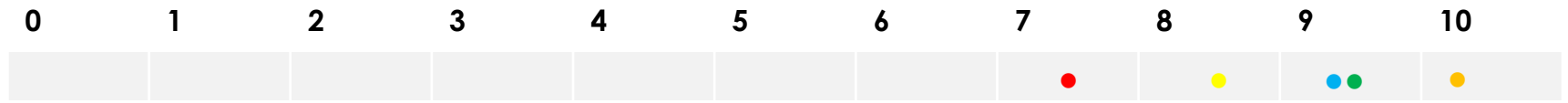
Admin Support	HCA	Nurse	Service Manager	Pharmacist	Board Member
		2	1	1	2

When you work on the new service how familiar does it feel?

Do you feel the new service is currently a normal part of your work?



Do you feel the new service will become a normal part of your work?



* Finch, T.L., Girling, M., May, C.R., Mair, F.S., Murray, E., Treweek, S., Steen, I.N., McColl, E.M., Dickinson, C., Rapley, T. (2015). Nomad: Implementation measure based on Normalization Process Theory. [Measurement instrument].

Staff feedback

Part C: Detailed questions about the implementation of the cholesterol management service

	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree	Not relevant to my role	Not relevant at this stage	Not relevant to the intervention
I can see how the new service differs from usual ways of working	●●	●	●					
Staff in this organisation have a shared understanding of the purpose of the new service	●	●●	●					
I understand how the new service affects the nature of my own work	●●	●						
I can see the potential value of the new service for my work	●●●	●						

Part C2

	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree	Not relevant to my role	Not relevant at this stage	Not relevant to the intervention
There are key people who drive the new service forward and get others involved	●●●●	●●						
I believe that participating in the organisation/delivery of the new service is a legitimate part of my role	●●●	●●●						
I'm open to working with colleagues in new ways to organise and/or deliver the new service	●●● ●●●							
I will continue to support the new service	●●● ●●●							

Staff feedback

Part C3

	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree	Not relevant to my role	Not relevant at this stage	Not relevant to the intervention
I can easily integrate the new service into my existing work								
The new service disrupts working relationships								
I have confidence in other people's ability to organise and/or deliver the new service								
Work is assigned to those with skills appropriate to the organisation and/or delivery of the new service								
Sufficient training is provided to enable staff to organise and/or deliver the new service								
Sufficient resources are available to support the organisation and/or delivery of the new service								
Management adequately supports the new service								

Part C4

	Strongly agree	Agree	Neither agree or disagree	Disagree	Strongly disagree	Not relevant to my role	Not relevant at this stage	Not relevant to the intervention
I am aware of reports about the effects of the new service								
The staff agree that the new service is worthwhile								
Feedback about the new service can be used to improve it in the future								

Conclusions/considerations

1. Implementing a new service such as this requires careful planning and the flexibility to adapt to challenges that arise. Regular project team meetings are an essential component of this and enable quality improvement methodology to be utilised in a cycle of continuous improvement.
2. Engaging with member practices/key stakeholders is an important factor for a service to be successful. Multiple channels have been used to achieve this i.e. email, educational webinars and face-to-face meetings. It is equally important to make it as simple as possible for participation to occur. MHH have provided data sharing agreements and have had support from the ICB central pharmacists' team, who have been able to run the searches remotely and reduce the additional burden on primary care.
3. It is important to have support from the wider system and to ensure any new service takes into consideration the wider care pathway. The clinics are targeting a specific high risk cohort but have a structure in place that ensures there is an opportunity to address the needs of those identified initially but unsuitable for the service.
4. The service has made progress within the period 03 January 2023 to 28 February 2023 (commencement of regularly scheduled clinics). Without appropriate planning and resource allocation this would not have been possible. Actively working with 9 of the 18 practices across the federation's geography is an indication of interest in the adoption of the new pathway with further expressions of interest received from other practices. However, it should be noted that those practices who have not yet engaged with the pathway were not included in this report, and their reasons are unknown.
5. Inclisiran was recommended by NICE in secondary prevention on 06 Oct 2021 and included in the local formulary for prescribing in primary care circa March 2022. 45% of all HIOW PCNs are prescribing inclisiran. Whilst the participant PCNs are prescribing a greater number of inclisiran items, we are unable to relate the early project findings regarding clinical experience of prescribing across the broader region until more patients receive the lipid management service.
6. This report does not have sufficient data to comment on the outcome of the implementation of the new pathway. A review of its impact will require an objective independent evaluation once more data is available.
7. To help establish the broader value of this service, it would be useful to track outcomes of the patients who have been referred back to their own practices for lipid optimisation, CVD risk review, lifestyle advice and alternative treatment options.

Appendices

NHS England Accelerated Access Collaborative - National Guidance for Lipid Management

Summary of National Guidance for Lipid Management for Primary and Secondary Prevention of CVD

ACCELERATED ACCESS COLLABORATIVE

NHS

INITIAL CONSIDERATIONS:

- Measure non-fasting ***full lipid profile*** (total cholesterol, HDL-C, non-HDL-C, triglycerides) and HbA1c as part of an initial baseline assessment.
- Consider secondary causes of hyperlipidaemia and manage as needed.
- Ensure appropriate baseline and follow up tests as detailed on page 2. Measure BMI.
- Identify and exclude people with contraindications/drug interactions
- If non-fasting triglyceride above 4.5mmol/L see page 2.

PRIMARY PREVENTION

Consider statin therapy for adults who do not have established CVD but fall into the categories below. Use QRISK risk assessment tool where appropriate (see page 2, *'Primary Prevention Risk Assessment'*)

- Age ≤84 & QRISK ≥10% over next 10 years
- Type 2 diabetes & QRISK ≥10% over next 10 years
- Type 1 diabetes, if they have one or more of the following:
  - Over 40 years
  - Had diabetes for >10 years
  - Have established nephropathy
  - Have other CVD risk factors
- CKD eGFR < 60 mL/min/1.73m² and/or albuminuria
- Age ≥85 years if appropriate consider comorbidities, frailty & life expectancy

Identify and address all modifiable risk factors - smoking, diet, obesity, alcohol intake, physical activity, blood pressure and HbA1c.

Consider additional risk factors, if present, together with QRISK score (treated for HIV, severe mental illness, taking medicines that cause dyslipidaemia, systemic inflammatory disorder (e.g. SLE), impaired fasting glycaemia, recent change in risk factors)

PRIMARY PREVENTION

If lifestyle modification is ineffective or inappropriate offer statin treatment.

Atorvastatin 20mg daily

- Measure full lipid profile again after 3 months (non-fasting).
- High intensity statin treatment should achieve reduction of non-HDL-C > 40% from baseline. If not achieved after 3 months;
  - discuss treatment adherence, timing of dose, diet and lifestyle
  - If at higher risk (based on comorbidities, risk score or clinical judgement – see page 2 *'Additional Risk Factors'*) consider increasing the dose every 2-3 months up to a maximum dose of atorvastatin 80mg daily.
  - For how to increase in people with CKD see *'Special Patient Populations'* (page 2).
- If patients on a high-intensity statin have side effects, offer a lower dose or an alternative statin (see page 2 *'Extent of lipid lowering with available therapies'*)
- If maximum tolerated dose of statin does not achieve non-HDL-C reduction > 40% of baseline value after 3 months consider adding Ezetimibe 10mg daily (NICE TA385)
- If statin treatment is contraindicated or not tolerated;
  - See AAC Statin Intolerance Algorithm for advice regarding adverse effects (click here)
  - Ezetimibe 10mg monotherapy may be considered. Assess response after 3 months.
  - Ezetimibe 10mg/bempedoic acid 180 mg combination may be considered when ezetimibe alone does not control non-HDL-C/LDL-C well enough (NICE TA694).

If non-HDL-C reduction remains < 40% of baseline despite maximal tolerated lipid lowering therapy (including people with intolerances and contraindications) consider referral to specialist lipid management clinic according to local arrangements

SEVERE HYPERLIPIDAEMIA

If TC>7.5mmol/L and/or LDL-C >4.9mmol/L and/or non-HDL-C >5.9mmol/L, a personal and/or family history of confirmed CHD (<60 years) and with no secondary causes: suspect familial hypercholesterolaemia (possible heterozygous FH)

Do not use QRISK risk assessment tool

DIAGNOSIS AND REFERRAL

Take fasting blood for repeat lipid profile to measure LDL-C.

Use the **Simon Broome** or **Dutch Lipid Clinic Network** (DLCN) criteria to make a **clinical diagnosis of FH**.

Refer to Lipid Clinic for further assessment if **clinical diagnosis of FH** or if TC>9.0mmol/L and/or LDL-C >6.5mmol/L and/or non-HDL-C >7.5mmol/L or Fasting triglycerides > 10mmol/L (regardless of family history) (page 2)

TREATMENT TARGETS IN FH

If clinical diagnosis of FH and/or other risk factors present follow the recommended treatment management pathway for primary or secondary prevention as for non-FH, ***BUT***

Aim to achieve at least a 50% reduction of LDL-C (or non-fasting non-HDL-C) from baseline.

Consider specialist referral for further treatment and/or consideration of PCSK9i therapy IF

- they are assessed to be at very high risk of a coronary event**
- OR therapy is not tolerated
- OR LDL-C remains >5mmol/L (primary prevention)
- OR LDL-C remains >3.5mmol/L (secondary prevention)

despite maximal tolerated statin and ezetimibe therapy.

**defined as any of the following:

- Established coronary heart disease
- Two or more other CVD risk factors

SECONDARY PREVENTION

Offer statin therapy to adults with CVD, this includes CHD, angina, Acute Coronary Syndrome (MI or unstable angina), revascularisation, stroke or TIA, or symptomatic peripheral arterial disease. Do not delay statin treatment if a person has acute coronary syndrome. Take a lipid sample on admission (within 24 hours).

Identify and address all modifiable risk factors - smoking, diet, obesity, alcohol intake, physical activity, blood pressure and HbA1c.

SECONDARY PREVENTION

Do not delay statin treatment in secondary prevention while managing modifiable risk factors.

Prescribe a high intensity statin:

Atorvastatin 80mg daily

Use a lower dose of atorvastatin if there is a potential drug interaction, high risk of or experiencing adverse effects, or patient preference.

Offer atorvastatin 20mg if CKD (people with GFR< 60 mL/min/1.73m²).

- Measure full lipid profile again after 3 months (non-fasting).
- High intensity statin treatment should achieve reduction of non-HDL-C > 40% from baseline. If not achieved after 3 months
  - discuss treatment adherence, timing of dose, diet and lifestyle measures
  - If started on less than atorvastatin 80mg and the person is judged to be at higher risk (based on comorbidities, risk score or clinical judgement - see page 2 *'Additional Risk Factors'*), consider increasing to 80mg atorvastatin. For how to increase in people with CKD see *'Special Patient Populations'* (page 2).
- If non-HDL-C baseline value is not available*, consider target non-HDL-C < 2.5mmol/L (approximately equivalent to LDL-C < 1.8mmol/L) as recommended by Joint British Societies (JBS3).
  **this scenario is not currently covered by NICE CG181. NICE will consider this as part of the guideline update with publication currently expected September 2023*
- If patients on a high-intensity statin have side effects, offer a lower dose or an alternative statin (see page 2 *'Extent of lipid lowering with available therapies'*)

If maximum tolerated dose of statin does not control non-HDL-C/LDL-C well enough after 3 months confirm statin adherence, then consider the following options based on shared decision making* with the patient

If recommended statin treatment is contraindicated or not tolerated - follow AAC Statin Intolerance Algorithm for advice regarding adverse effects (click here).

If statin intolerance is confirmed, consider:

- **Ezetimibe 10mg** monotherapy. Assess response after 3 months (TA385)
- **Ezetimibe 10mg/bempedoic acid 180 mg** combination when ezetimibe alone does not control non-HDL-C sufficiently. (NICE TA694)

If non HDL-C remains > 2.5mmol/L despite other lipid lowering therapies consider Injectable therapies - arrange a fasting blood test and assess eligibility criteria (TA393/394, TA733)

Ezetimibe 10mg daily (NICE TA385). Reassess after three months. If non-HDL-C remains > 2.5mmol/L; consider **injectable therapies** arrange a fasting blood test and assess eligibility

Injectable therapies**

If non-HDL-C > 2.5mmol/L; Arrange fasting blood test to measure LDL-C to assess eligibility:

- **Inclisiran** - if fasting LDL-C ≥ 2.6mmol/L despite maximum tolerated lipid lowering therapy (TA733)

OR

- **PCSK9i** - see overleaf for LDL-C thresholds. (TA393/4)

If eligibility criteria not met, consider **ezetimibe 10mg daily** (if not previously considered)

* See overleaf for information to support shared decision making

** Inclisiran and PCSK9i should not be prescribed concurrently

Additional CV risk reduction considerations - check fasting triglycerides levels and consider icosapent ethyl. See triglycerides section overleaf.

NHS England Accelerated Access Collaborative - National Guidance for Lipid Management

MANAGEMENT

This guidance applies to new patients and may also be taken into consideration for those already on statins at their annual review. If 40% reduction of non-HDL-C not achieved, offer high intensity statins. Discuss with people who are stable on a low- or medium-intensity statin the likely benefits and potential risk of side effects if changed to a high-intensity statin when they have a medication review and agree with the person whether a change is needed.

Ezetimibe, alirocumab, evolocumab or inclisiran can be added when patients' LDL-C levels are not lowered enough with the maximally tolerated dose of statins. Bempedoic acid with ezetimibe is an option when statins are contraindicated or not tolerated, and when ezetimibe alone does not control LDL-C well enough. Do not offer a fibrate, nicotinic acid, bile acid binder or omega-3 fatty acids alone or in combination with statin, for the prevention of CVD (check NICE CG181 and TA805 for exceptions).

PRIMARY PREVENTION RISK ASSESSMENT

QRISK3 is the current version of the QRISK calculator. www.qrisk.org/three

- Do not use this risk assessment tool for people with established CVD or those who are at high risk of developing CVD because of FH or other inherited disorders of lipid metabolism.
- Do not use a risk assessment tool to assess CVD risk in people with type 1 diabetes, or eGFR less than 60 mL/min/1.73 m^2 and/or albuminuria.
- Consider people aged ≥ 85 at increased risk of CVD because of age alone particularly people who smoke or have raised BP.

Additional Risk Factors

Note, standard CVD risk scores including QRISK may underestimate risk in people who have additional risk because of underlying medical conditions or treatments. These groups include the following groups of people;

- severe obesity (BMI>40kg/m^2) increases CVD risk
- treated for HIV
- serious mental health problems
- taking medicines that can cause dyslipidaemia such as antipsychotic medication, corticosteroids or immunosuppressant drugs
- autoimmune disorders such as SLE, and other systemic inflammatory disorders
- non-diabetic hyperglycaemia
- significant hypertriglyceridaemia (fasting triglycerides 4.5-9.9mmol/L)
- recent risk factor changes e.g. quit smoking, BP or lipid treatment

Consider socio-economic status as an additional factor contributing to CVD risk.

If QRISK < 10% over the next 10 years - Give lifestyle advice and ensure regular review of CVD risk in line with guidance.

SPECIAL PATIENT POPULATIONS

Type 1 Diabetes

While NICE recommends offering statins to patients with Type 1 diabetes as detailed in the algorithm, it also states to consider statins in all adults with type 1 diabetes.

Chronic Kidney Disease

Offer atorvastatin 20mg for the primary or secondary prevention of CVD to people with CKD (eGFR less than 60 mL/min/1.73m^2 and/or albuminuria)

Increase the dose if a greater than 40% reduction in non-HDL-C is not achieved and eGFR is 30 mL/min/1.73m^2 or more.

Agree the use of higher doses with a renal specialist if eGFR is less than 30 mL/min/1.73m^2

ABBREVIATIONS

ALT: alanine aminotransferase
AST: aspartate aminotransferase
CHD: coronary heart disease
CKD: chronic kidney disease
CVD: cardiovascular disease
FH: familial hypercholesterolaemia
LDL-C: low density lipoprotein cholesterol
non-HDL-C: non-high density lipoprotein cholesterol
PCSK9i: proprotein convertase subtilisin kexin 9 monoclonal antibody inhibitor
SLE: systemic lupus erythematosus
SPC: summary of product characteristics
TC: total cholesterol

EXTENT OF LIPID LOWERING WITH AVAILABLE THERAPIES

Approximate reduction in LDL-C					
Statin dose mg/day	5	10	20	40	80
Fluvastatin			21%	27%	33%
Pravastatin		20%	24%	29%	
Simvastatin		27%	32%	37%	42%
Atorvastatin		37%	43%	49%	55%
Rosuvastatin	38%	43%	48%	53%	
Atorvastatin + Ezetimibe 10mg		52%	54%	57%	61%

Low intensity statins will produce an LDL-C reduction of 20-30%
Medium intensity statins will produce an LDL-C reduction of 31-40%
High intensity statins will produce an LDL-C reduction above 40%
Simvastatin 80mg is not recommended due to risk of muscle toxicity

- **Rosuvastatin** may be used as an alternative to atorvastatin if compatible with other drug therapy. Some people may need a lower starting dose (see BNF).
- Low/medium intensity statins should only be used if intolerance or drug interactions.
- **Ezetimibe** when combined with any statin is likely to give greater reduction in non-HDL-C or LDL-C than doubling the dose of the statin.
- **PCSK9i** (NICE TA393, TA394) alone or in combination with statins or ezetimibe produce an additional LDL-C reduction of approximately 50% (range 25-70%).
- **Bempedoic acid** when combined with ezetimibe (TA694) produces an additional LDL-C reduction of approximately 28% (range 22-33%) but no clinical outcome evidence is currently available.
- **Inclisiran** (TA733) alone or in combination with statins or ezetimibe produces an additional LDL-C reduction of approximately 50% (range 48-52%) but no clinical outcome evidence is currently available.

MONITORING

Baseline Measurements

In addition to full lipid profile, measure renal, thyroid and liver profiles (including albumin) and HbA1c to exclude secondary causes and co-morbidities.
Measure baseline liver transaminase (ALT or AST) before starting a statin.
Measure CK if unexplained muscle pain before starting a statin.
CK should not be measured routinely especially if a patient is asymptomatic.

	Primary Prevention		Secondary prevention	
	Lipid Profile	ALT or AST	Lipid Profile	ALT or AST
Baseline	✔	✔	✔	✔
3 months	✔	✔	✔	✔
6-9months	If <40% non-HDL-C reduction, up titration required. Repeat full lipid profile and ALT or AST within 3 months of each up-titration of statin dose or addition of ezetimibe as required			
12 months	✔	✔	✔	✔
Yearly	✔*		✔*	

Provide annual medication reviews for people taking statins to discuss effectiveness of therapy, medicines adherence, lifestyle modification and address CVD risk factors.
Consider an annual non-fasting **full lipid profile to inform the discussion around effectiveness of lipid lowering therapy and any medicines non-adherence.*

Monitoring

Repeat full lipid profile is non-fasting.
Measure liver transaminase within 3 months of starting treatment and then within 3 months of every additional up titration and then again at 12 months, but not again unless clinically indicated.

If ALT or AST are greater than 3 times the upper limit of normal then do not initiate a statin or discontinue statin therapy already prescribed and repeat the LFTs in a month.

If ALT or AST are elevated but are less than 3 times the upper limit of normal then:

- Continue the statin and repeat in a month.
- If they remain elevated but are less than 3 times the upper limit of normal then continue statin and repeat again in 6 months.

TITRATION THRESHOLD / TARGETS

	NICE titration threshold	JBS3
Primary prevention Secondary Prevention	Intensify lipid lowering therapy if non-HDL-C reduction from baseline is less than 40%	non-HDL-C <2.5mmol/L (LDL-C <1.8mmol/L)
FH	Optimise lipid lowering therapy to achieve at least 50% reduction in LDL-C (or non-HDL-C.)	

If baseline cholesterol is unknown in the setting of secondary prevention use the use Joint British Societies' JBS3 consensus recommendation.
Non-HDL-C = TC minus HDL-C
LDL-C = non-HDL-C minus (Fasting triglycerides[a]/2.2)
[a] valid only when fasting triglycerides are less than 4.5 mmol/L

SPECIALIST SERVICES

Scope of specialist service available locally may include; lipid clinic, PCSK9i clinic (offering initiation and subsequent follow up), FH genetic diagnosis and cascade testing, lipoprotein apheresis service. NICE eligibility criteria for PCSK9i and fasting LDL-C thresholds are summarised below.

NICE TA393 Alirocumab NICE TA394 Evolocumab	Without CVD	With CVD	
		High risk [1]	Very high risk [2]
Primary non-FH or mixed dyslipidaemia	Not recommended	LDL C > 4.0 mmoL/L	LDL C > 3.5 mmoL/L
Primary heterozygous-FH	LDL C > 5.0 mmoL/L	LDL C > 3.5 mmoL/L	

[1] History of any of the following: ACS; coronary or other arterial revascularisation procedures; CHD, ischaemic stroke; PAD. [2] Recurrent CV events or CV events in more than 1 vascular bed (that is, polyvascular disease).

Bempedoic acid/ezetimibe and inclisiran are available in primary care and do not require initiation by specialist services.* PCSK9i may be available for prescribing in primary care: see local initiation pathways.

TRIGLYCERIDES

Triglyceride concentration	Action
Greater than 20mmol/L	**Refer to lipid clinic for urgent specialist review** if not a result of excess alcohol or poor glycaemic control. At risk of acute pancreatitis.
10 - 20mmol/L	Repeat the TG measurement with a fasting test (after an interval of 5 days, but within 2 weeks) and review for potential secondary causes of hyperlipidaemia. Seek specialist advice if the TG concentration remains > 10mmol/litre. At risk of acute pancreatitis
4.5 - 9.9mmol/L	If non-fasting triglycerides are greater than 4.5mmol/L, repeat with a fasting TG measurement Be aware that the CVD risk may be underestimated by risk assessment tools, optimise the management of other CVD risk factors present and seek specialist advice if non-HDL-C concentration is > 7.5 mmol/litre.

Icosapent ethyl (TA805)
- Check fasting triglycerides levels.
- Manage secondary causes of hypertriglyceridaemia.
- Consider icosapent ethyl (TA805) if patient has established cardiovascular disease (secondary prevention) and
  - on statins and fasting TG ≥ 1.7mmol/L and LDL-C* between 1.04‡ and ≤2.6mmol/L
- See table above and refer as appropriate.

* LDL-C cannot be calculated using Friedewald's formula if TG >4.5. Discuss with your lab. Consider using an alternative equation (eg Sampson, doi: 10.1001/jamacardio.2020.0013) or beta-quantification.
‡ labs don't report calculated LDL-C beyond one decimal point

STATIN INTOLERANCE

Statin intolerance is defined as the presence of clinically significant adverse effects from statin therapy that are considered to represent an unacceptable risk to the patient or that may result in adherence to therapy being compromised.

For people who are intolerant of the recommended statin treatment see the NHSE AAC statin intolerance algorithm, available on the NHSE AAC page (Click here)

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NICE 2021. TA733 www.nice.org.uk/guidance/TA733
NICE 2022. TA805 www.nice.org.uk/guidance/ta805

Authors: Dr Rani Khatib & Dr Dermot Neely on behalf of the AAC Clinical Subgroup.

Nov 2022. Review date: Nov 2023.

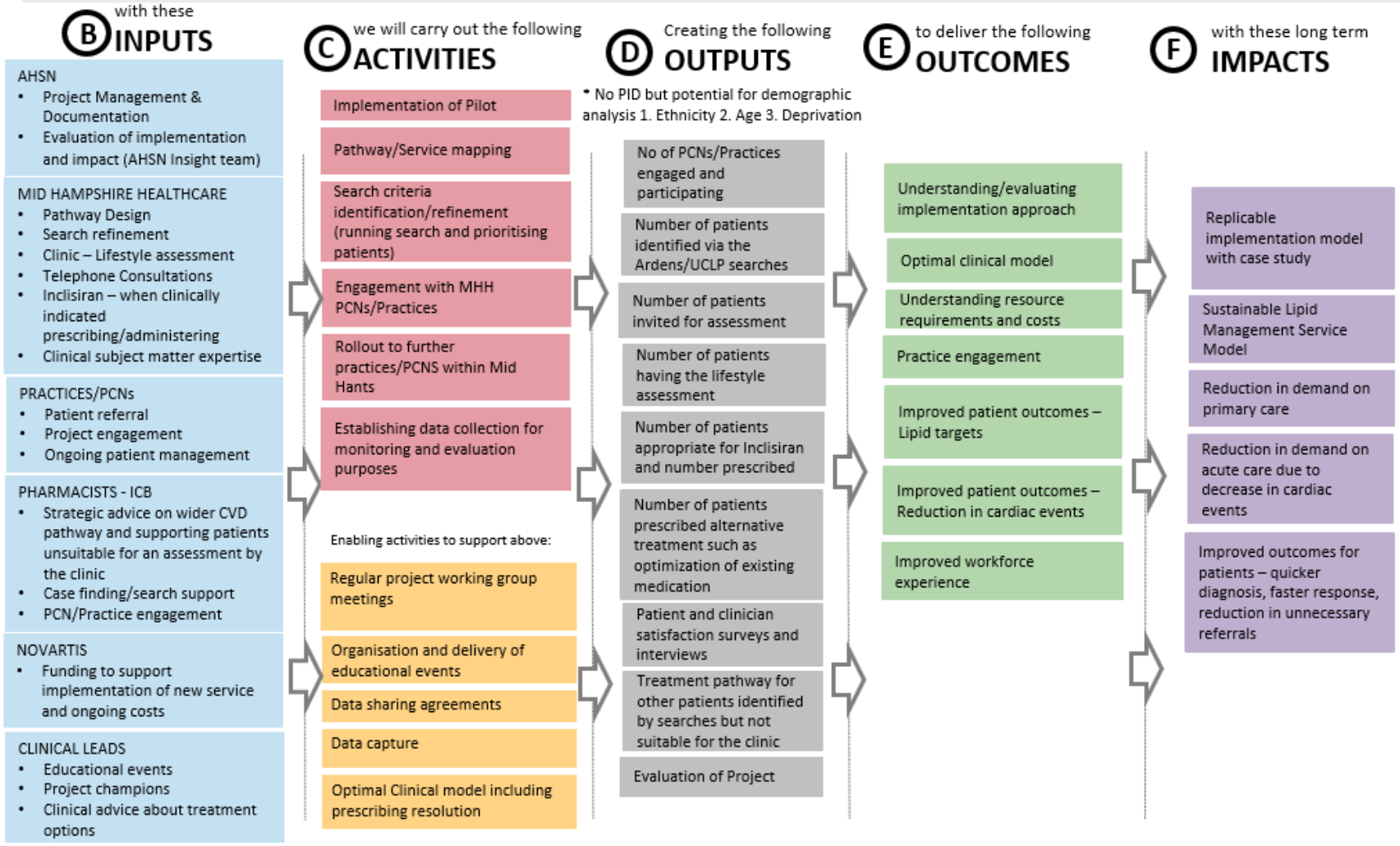
NICE confirmed that its guidance is accurately represented, Nov 2022.

Mid Hampshire Healthcare - Lipid Clinic Project Logic Model

MHH LIPID CLINIC PROJECT

A Our CONTEXT and RATIONALE

Mid Hampshire Healthcare (MHH) is introducing a new cholesterol management service to support patients with secondary Atherosclerotic cardiovascular disease (ASCVD) . Patients are identified via searches run within the practices' clinical systems (all 18 member practices have been invited to participate) and are then invited to attend a cardiovascular health check and follow up telephone consultation to agree a treatment plan which may or may not include the drug Inclisiran. The aim is to enable improved control of cholesterol and reduce risk of secondary events or complications.



Mid Hampshire Healthcare - Initial correspondence to practices

Mid Hampshire Healthcare

Basepoint Business Centre
1 Winnall Valley Road
Winchester
SO23 0LD

05 April 2022

Dear Practices,

PROPOSED NEW SERVICE – CHOLESTEROL MANAGEMENT

In light of the new lipid management pathway (https://www.england.nhs.uk/aac/wp-content/uploads/sites/50/2020/04/Lipid-Management-Pathway-NEW-version-4.pdf), we have been working collaboratively with Dr John Bolodeoku, Consultant Lipidologist at HHFT, Wessex AHSN and Novartis about the future of cholesterol management/lipid management within Primary Care and how the new treatment, Inclisiran, could be taken on by Primary Care as part of wider population health management.

As you are aware, cardiovascular disease is a top priority within NHSE but also for our local ICS. With the launch of a new treatment targeted specifically at primary care, we have been looking at how we could support patients who have secondary Atherosclerotic cardiovascular disease (ASCVD), initially, in a scalable primary care model.

Our aim is to create a cholesterol management service that you can access for your patients, enabling improved control of their cholesterol and therefore reducing patient risk of secondary events or complications but also enabling a remuneration back into practice to support the administrative role as well as giving you renumeration for sending your patients to our clinics.

Cholesterol management is now a PCN DES requirement and therefore, this service development may give PCNs a service able to meet this requirement from day 1 [https://www.england.nhs.uk/wp-content/uploads/2022/03/B1357_iii-network-contract-directed-enhanced-service--cardiovascular-disease-prevention-and-diagnosis-suppl.pdf].

What is Inclisiran?

Inclisiran was launched by NHSE and the AHSNs in September. NICE TA733 (6th October 2021) recommends Inclisiran as an option for treating primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia as an adjunct to diet in adults. However, it is currently only recommended if:

a) There is a history of ischaemic stroke, coronary heart disease or peripheral arterial disease and

b) Low-density lipoprotein cholesterol (LDL-C) concentrations are persistently 2.6 mmol/l or more, despite maximum tolerated lipid-lowering therapy.

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Inclisiran is administered as a subcutaneous injection into the abdomen, upper arm or thigh. The recommended dose is 284mg Inclisiran loading dose at 0 months and 3 months, then long-term maintenance every 6 months. It is intended for administration by a Healthcare Professional, not the patient. No additional monitoring is required.

This is an opportunity for patients in the Mid Hampshire Region to benefit from a new drug which has the potential to offer cholesterol-lowering treatment to those who have not been able to achieve a lowering of their cholesterol either through lifestyle changes or through the use of traditional cholesterol lowering medication.

It can be used in combination with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated other lipid-lowering therapies, in patients who are statin-intolerant, or for whom a statin is contraindicated.

The product was launched by the NHS instead of the pharmaceutical company, Novartis, as NHSE wanted to launch under the population health umbrella directing its usage at Primary Care. Novartis have been supporting our conversation and service proposal.

Inclisiran is listed as GREEN on the Hampshire, Southampton and IOW Formulary.

Clinical Support

In partnership with the AHSN and Dr John Bolodeoku, we are creating some bespoke educational launching events on lipids and inclisiran that will give you further detail into the treatment itself.

Continuing educational events and Webinars will be made available for continual educational developments of primary care teams around cholesterol management, which will include case studies and treatment challenges.

What is the service proposal?

A cholesterol management service running within daytime or out of hours clinics, where MHH would provide full management of patients through the following appointment structures:

1. A Cardiovascular Health check looking at;
    a. Lifestyle
    b. Adherence to medication
    c. BP/BMI
    d. Initiation/completion of bloods
2. A clinician-led telephone consultation review with the patient to consider management plan which could be either:
    a. Titrate up medication or add in alternative treatments if not a maximum tolerated therapy and discharge back to practices; or
    b. Identify those who are tolerating maximum therapy and where Inclisiran would be the next treatment option.

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3. Inclisiran appointments and injection administration managed by MHH
4. Full consultation documentation recorded on patients' medical records and emailed back to practice

Collaborative working with HHFT lipidologists will be undertaken with any complex patients and a regular MDT meeting undertaken with the MHH clinical team and HHFT

Eligible patients can be found via an Ardens search (this is currently in creation).

Current guidance is that there are approximately 5 patients in every 1000 eligible for Inclisiran.

Attached is a rough draft of how we envisage this service working.

NB: Inclisiran as a treatment is a twice-yearly injection. Within the above proposal, we will manage the recall process of patients initiated on treatment and requiring ongoing appointments.

Financial Details

At the moment there is no available funding for the development of a cholesterol management service.

There is a reimbursement mechanism for inclisiran that covers the cost of the drug and a dispensing fee. MHH is able to claim this reimbursement cost directly and will use this initially to fund the service, and to support training of staff in cardiovascular management.

To help support practices in identifying and inviting patients, we intend to pay a small administration fee for every patient who commences on Inclisiran therapy. This will be paid on a quarterly basis.

What is the ask from Practices?

Initially, we are looking for engagement with this proposal to enable us to move forward.

We would be grateful if you could answer the below;

- Is this something that you would be happy for us to develop?
- Are you happy to run searches within Ardens and invite patients for an appointment?
- Do you have any clinical room space available, if so when and what times?

If we are able to develop this service, all that we will ask from you is to run Ardens searches and invite the highest risk eligible patients into a CVD Health check appointment with MHH.

Mid Hampshire Healthcare - Patient Satisfaction Questionnaire

Mid Hampshire Healthcare

Patient Satisfaction Questionnaire

Dear Patient, we would be grateful if you would complete this questionnaire about your journey on the Cardiac Risk Pathway. Feedback from this survey will enable us to identify areas that may need improvement. Your opinions are therefore very valuable.

Please answer **all** the questions below. There are no right or wrong answers and we will **not** be able to identify your individual responses.

	Not relevant to this consultation	☹ No, not at all	No, not really	😐 Yes, but not fully	Yes	☺ Yes, completely
The service has given me an increased knowledge and awareness relating to my cholesterol levels.	Not Applicable	No, not at all	No, not really	Yes, but not fully	Yes	Yes, completely
At every stage of the process things were explained to me in a clear and concise manner.	Not Applicable	No, not at all	No, not really	Yes, but not fully	Yes	Yes, completely
Were you involved as much as you wanted to be in decisions about your care and treatment?	Not Applicable	No, not at all	No, not really	Yes, but not fully	Yes	Yes, completely
Do you have confidence in the decisions made about your cholesterol levels or treatment?	Not Applicable	No, not at all	No, not really	Yes, but not fully	Yes	Yes, completely
At every stage of the process were you encouraged to ask questions?	Not Applicable	No, not at all	No, not really	Yes, but not fully	Yes	Yes, completely
Were all of your questions answered to a level you were satisfied with?	Not Applicable	No, not at all	No, not really	Yes, but not fully	Yes	Yes, completely
Were you treated with respect and dignity at every stage of the process?	Not Applicable	No, not at all	No, not really	Yes, but not fully	Yes	Yes, completely
Is your treatment so far achieving the desired results?	Not Applicable	No, not at all	No, not really	Yes, but not fully	Yes	Yes, completely
Overall have your experiences with Mid Hampshire Healthcare's new Lipid management service been satisfactory.	Not Applicable	No, not at all	No, not really	Yes, but not fully	Yes	Yes, completely

The implementation of Mid Hampshire Healthcare's new service is being evaluated by the Wessex Academic Health Science Network (AHSN). This will help other organisations to replicate the service in their own area and enable more patients to benefit. Would you be happy to have a follow up interview with Wessex AHSN to discuss your experiences in more detail.

Yes	No

Your views will be anonymised in the findings and report and all information that we use will be processed in accordance with the Data Protection Act (2018).

Do you have any specific comments about your experiences with the service to date?

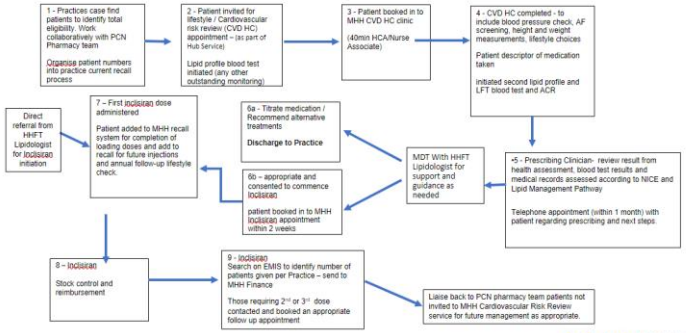
Mid Hampshire Healthcare – Service summary slides for educational webinars

NHS

MHH Cardiovascular Risk Review Pathway

September 2022

Mid Hampshire Healthcare



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Mid Hampshire Healthcare

www.midhampshirehealthcare.co.uk

Working on behalf of Andover, Winchester City, Rural North & East and Rural South GP Practices

SUMMARY

PRACTICE REQUIREMENTS

- Include routine inclusion of lipid profile blood test in all management of cardiovascular chronic disease blood monitoring
- Run EMIS ARDEN/UCL Searches each month and identify all patients not adequately controlled on current lipid therapy
- Initiate lipid profile blood test along with any other outstanding monitoring blood tests on patient bookings
- Book patient direct into MHH Cardiovascular Assessment clinic with HCA/Nurse Associate

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SUMMARY

MHH ACTIVITY

- Undertake a Lifestyle assessment including BMI, Blood Pressure, AF screening, smoking, alcohol consumption, documentation of patient medication descriptor. Motivational and positive engagement with external services to encourage health improvements where applicable
- Initiate second Lipid Profile Blood Test along with any other follow-up monitoring blood tests and ACR
- Book patient direct into MHH Clinical prescriber Cardiovascular Review Consultation
- MHH GP Clinical review of patient records and telephone consultation with patient regarding medication changes, or initiation of NICE approved medications including Inclisiran (refer back to Practice/discuss with HHFT Lipidologist where specialist guidance as required)
- Where Inclisiran consented booked with Practice Nurse within 2 weeks for initial dose

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SUMMARY

MHH ADMINISTRATION

- All recalls applied within MHH EMIS system to recall the patient for each dose and annual cardiovascular risk review
- Stock control to ensure the availability of Inclisiran at each patient appointment
- Patients invited to MHH appointment for administration of Inclisiran and annual cardiovascular risk review
- Liaise with PCN pharmacy team patients identified on secondary prevention searches not included in the MHH cardiovascular risk review service for future management

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BENEFITS FOR PRACTICES

- Help improve QOF achievements for blood pressure records, smoking status, obesity register
- Supporting practices to meet the PCN DES improving lipid optimisation in high risk patients, detection of atrial fibrillation and hypertension optimisation
- Reduce time within practice to undertake cardiovascular risk assessments
- HHFT lipidologist support in the specialist management of patients through MDT

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Working on behalf of Andover, Winchester City, Rural North & East and Rural South GP Practices

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